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**J.A. HINES**

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STATE REPRESENTATIVE • 42ND ASSEMBLY DISTRICT

**Testimony Before the Assembly Committee on Public Health in  
Support of Assembly Bill 492**

Good afternoon. I would like to thank Senator Taylor for joining me today to testify in support of this extremely important piece of legislation, Assembly Bill 492.

As Chairman of the Assembly Committee on Public Health, I have always believed that the key to Wisconsin's successful public health system is prevention. One of the best things we can do as a state is to make sure people have the information they need to make smart decisions about protecting their health, whether we're talking about the avian flu or cervical cancer. This bill does exactly that and that is why I agreed to be the Assembly author.

By providing parents with information about the HPV virus, how it spreads, and information on the availability and effectiveness of a vaccine, we can eventually prevent thousands of women from suffering the awful consequences of cervical cancer. Some believe that we are mandating this vaccine, but we are not and I hope we can eliminate that confusion here today. Parents will be the ones to decide whether their daughter will receive the vaccine or not, but I believe it only makes sense that they have all the information available to make an educated decision.

This bill isn't partisan, it's just common sense and I think you can easily see that by the legislators and individuals that are here to testify and register in favor of the bill today.

Wisconsin has always been a national leader when it comes to public health and this bill will only strengthen that fact. I am proud to be a part of this effort and proud to be the Assembly author.

I ask you to join Senator Taylor and me in supporting this bill and voting in favor of it when the time comes both in committee and on the floor of the Assembly.





# LENA C. TAYLOR

Wisconsin State Senator • 4th District

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HERE TO SERVE YOU!

Dear Committee Members,

I greatly appreciate the opportunity to testify here today. I am even more appreciative of the bipartisan effort that has led to this great day. It is because of the efforts and dedication of people like Rep. Hines that we can stand here today and take our first steps toward the complete elimination of cervical cancer!

As many of you know, cervical cancer is the second most common cancer among women. Each year over 11,000 of our mothers, sisters, and friends contract this horrible disease. Of those, nearly 4,000 will die, and countless others will be left with deep emotional and physical wounds that last a lifetime. Now is the time for action, and at long last we have a real weapon in the fight against cancer.

Over the past several years drug companies have been hard at work developing a vaccination against the Human Papilloma Virus, the virus that causes cervical cancer. HPV is a disease that strikes over 50% of sexually active adults, and leaves few if any warning signs. Left untreated, however, this virus can develop into cancerous cells, and eventually become fatal. We now have the ability to prevent that from happening!

The legislation you have before you will launch a statewide education campaign, giving parents and guardians the information they need to decide if this vaccine is right for their children. It will provide accurate medical facts, and encourage families to talk to their doctors about the potential benefits and risks of the vaccine. As elected officials, one of our highest responsibilities is to educate the public, and help them make good decisions about their own well-being.

I realize that an issue like children's vaccinations will always generate a great deal of apprehension. Fortunately, this vaccination has been given a tremendous amount of scrutiny by the medical community, and has passed every test. The initial study for this vaccination was conducted on over 20,000 individuals, one of the largest populations for any such test. Since its approval by the FDA, the Advisory Committee on Immunization Practices, and the Center for Disease Control, over 2 million doses have been shipped off and administered without incident.

During this process I have had extensive conversations with doctors, medical experts, and health advocates. They have reassured me of both the safety of the new vaccines and their effectiveness. In fact, following the vaccine's introduction, the Medical College of Wisconsin, the Wisconsin Medical Society, and the Wisconsin Nurses Association have all registered in support of this bill.

In closing, we have a great opportunity today to help end cervical cancer for the next generation of women. I am proud to be part of this historic effort, and thank the many individuals who have worked so hard to make this day possible. Our actions here today prove that despite our many differences, we can work together to create a brighter future for the people of Wisconsin.





# W.A.C.S.

**WISCONSIN ASSOCIATION OF CHRISTIAN SCHOOLS, INC.**  
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Testimony before the Committee on Public Health September 26, 2007  
by Marvin L Munyon

I appreciate the opportunity to testify before this committee hearing and express my concerns about AB 492 & the Senate companion bill SB 252. I am the founder and president of Wisconsin Capitol Watch, and serve as the Legislative Representative for the Wisconsin Association of Christian Schools (WACS) and am speaking on their behalf today.

Many churches and Christian schools are working hard to educate and keep teens from becoming sexually active. They are working with teens and their parents to promote programs to teach and train teens to refrain from sexual activity and to practice abstinence. There are also a number of programs designed to help teens that have already become sexually active to change this behavior, practice abstinence and live without exposing themselves to all the dangers that come with being sexually active including cervical cancer, STDs, pregnancy and abortion. We believe abstinence outside of marriage is the only sure way to prevent these dangers. We would also encourage the legislature to urge Governor Doyle to reinstate the abstinence funding which has been dropped.

Gardasil, the HPV vaccine offered and promoted by the pharmaceutical company Merck is much in the news today all across this country and Canada. A number of states are seeking to mandate this vaccine to all girls entering the 6<sup>th</sup> grade in an attempt to prevent and curb the papillomavirus which can lead to or be associated with cervical cancer. Many believe this vaccine has not received adequate testing and there are many adverse effects being reported and some deaths have been attributed to the vaccine. It is interesting that Merck has achieved immunity from lawsuits which can create a huge liability for taxpayers. We believe mandating and disseminating information about HPV and Gardasil sends the wrong message to young girls and can lead to a sexually active life style because they believe they are protected with this vaccine.

It is worthy to note that HPV is not the same as other contagious disease vaccines. HPV is a sexually transmitted disease and according to the CDC is "primarily transmitted by genital contact, usually through sexual intercourse." "In virtually all studies of HPV prevalence and incidence, the most consistent predictors of infection have been measures of sexual activity, most importantly the number of sex partners." It is also worthy to note that under chapter 948 of Wisconsin law, stiff penalties apply to those who would exploit a child or have sexual intercourse with a child who has not attained the age of 18.

This legislation mandates that every private school provide the parents and guardians of pupils enrolled in grades 6 - 12 in the school with the information made available by DPI. The requirement may be satisfied by posting the information on the private school's Internet site. We do not know what this information will consist of as it is yet to be collected. We are concerned this will mandate our non-public, private schools to display on our Internet sites and distribute information and speech which is contrary to our religious beliefs.

Private school law in s. 118.165 (1)(d) contains the following language; "This subsection does not require the program to include in its curriculum any concept, topic or practice in conflict with the program's religious doctrines or to exclude from its curriculum any concept, topic or practice consistent with the program's religious doctrines." This proposed mandated information could certainly be in conflict with our program's emphasis on abstinence of all sexual activity outside of marriage.

The Wisconsin State Constitution also highly protects religious conscience in Article I Section 18 with these words:

The right of every person to worship Almighty God according to the dictates of conscience shall never be infringed; ...nor shall any control of, or interference with, the rights of conscience be permitted....

The Wisconsin Supreme Court also safeguards religious conscience and in *State v. Miller* expressed these words;

"In recognition of the state's unique history, the drafters of our constitution created a document that embodies the ideal that the diverse citizenry of Wisconsin shall be free to exercise the dictates of their religious beliefs." The Court applies strict scrutiny to laws that violate rights of conscience and this appears to be a stricter scrutiny of protection of religious conscience than the First Amendment of the U.S. Constitution which states:

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech....

We believe mandating private schools to make this information available to our parents and thus students sends the wrong message. First it presumes that many if not all students in grades 6 - 12 are sexually active or will be. It also interferes with the parent/child/physician relationships. Specifics of sexually transmitted diseases is not a topic we believe our private school personnel have the expertise to explain or should be responsible for.

In light of these three examples of religious conscience and free speech protections, we ask that you carefully consider the possible violations of religious conscience and free speech and provide a religious exemption to non-public, private schools from this mandate.

Many churches and Christian schools are seeking to strengthen their families and nurture the traditional values they hold dear. This proposed legislation directly conflicts with these values and beliefs which divides and undermines families rather than strengthening families.

We urge the committee to provide an exemption for non-public, private schools from this mandated reporting of HPV information. Thank you for opportunity to speak at this hearing.

Sincerely,



Marvin L Munyon  
WACS Legislative Representative

Archdiocese of Milwaukee

Association of  
Christian Schools International

Christian Schools International

Diocese of Green Bay

Diocese of LaCrosse

Diocese of Madison

Diocese of Superior

Lutheran Church  
Missouri Synod  
North Wisconsin District

Lutheran Church  
Missouri Synod  
South Wisconsin District

Wisconsin Association of  
Independent Schools

Wisconsin Conference of  
Seventh Day Adventists

Wisconsin Evangelical  
Lutheran Synod  
Northern Wisconsin District

Wisconsin Evangelical  
Lutheran Synod  
Western Wisconsin District

Wisconsin Evangelical  
Lutheran Synod  
Southeastern Wisconsin District

To: Assembly Public Health Committee  
From: Matt Kussow, Executive Director  
WCRIS  
Re: Opposition to AB492  
Date: September 26, 2007

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The Wisconsin Council of Religious and Independent Schools (WCRIS) is opposed to Assembly Bill 492 relating to requiring schools to provide information about the human papillomavirus to parents of pupils in grades 6 to 12.

On Monday, September 18, the WCRIS Board of Directors voted unanimously to oppose AB492 based on the grounds that it is an unfunded mandate which compromises the unique curriculums of individual schools to approach the subject of sex education on their own agendas.

The Board recognized the significant shift of the proposal from mandating vaccination against the virus to providing information to the parents of children in grades 6 to 12 as an improvement. However, several concerns still exist.

Many religious and independent schools promote abstinence in the literature and instruction they provide to their students. Mailing or posting information about a sexually transmitted disease on their websites, and describing a vaccination for such a disease, would conflict with their current curriculum and the message they promote in their church and communities. We feel providing such information would be viewed as sponsoring, or even promoting such discussions.

In addition, most religious and independent schools have established guidelines as to what age sexual education is taught in the classroom. Although WCRIS recognizes this information is to be provided to parents outside the classroom, the leadership role our schools would be taking in providing the information to sixth grade students conflicts with such guidelines.

WCRIS respectfully requests the Committee to consider an opt-out provision for religious and independent schools which have philosophical concerns with providing this information.

Thank you for your consideration.





PUBLIC HEARING ON SEPTEMBER 26, 2007 1:15 PM  
LOCATION: CAPITOL BUILDING IN MADISON, ROOM 328 NORTHWEST  
HELD BY THE COMMITTEE ON PUBLIC HEALTH IN THE ASSEMBLY

Chairman of the Assembly Public Health Committee:

Members of the Assembly Public Health Committee:

Legislators of the State of Wisconsin:

Fellow citizens of Wisconsin:

My name is Marian Ten Pas and I live in Oostburg, WI and I am here to speak in opposition to Assembly Bill 492 and its companion bill Senate Bill 252. This bill would mandate the State Department of Health and Family Services (DHFS) to collect information about the human papillomavirus (HPV) including the causes and symptoms of the virus, how it is spread, how it may be prevented, how to obtain additional information about the virus and the availability, effectiveness and risks of vaccination against the virus. The DHFS would then have to make the collected information available to public schools, private schools, and charter schools. Then each school board or governing body of each public, private, and charter school would have to provide the collected information to the parents and guardians of all pupils enrolled in grades 6 to 12. The HPV, spread only by sexual activity, leads to cervical cancers. The bill has the stated goal of preventing or curing those cancers. I speak as a Mother, Grandmother, and as a woman who loves kids. There are several reasons why I oppose this bill.

1. AB 492 would require every single school- public, private, and charter, to promote a vaccine manufactured by a single company, Merck. When and how did it become the responsibility of ordinary taxpayers to help one private company? Would this expand to taxpayers paying another drug company for promoting their drug, or another manufacturer to promote their car seat for kids, or their bicycle, because it was mandated by the Wisconsin Legislature? Since Merck has a record of marketing unsafe drugs, which resulted in those drugs being taken off the market, it is even more important that we residents of Wisconsin not be forced to support that company. Therefore it is not the

duty nor right for the Wisconsin Assembly and/or Senate to promote the drug manufacturer, Merck.

2. *Gardasil*, the Merck drug that AB 492 would require every school and all parents of Junior High and High School age students to be informed about, has not even been proven to be safe. It was "approved" by the Food and Drug Administration in June, 2006 for females aged 9 to 26 after only a six month review. In the clinical trials, there were 25,000 subjects. *Gardasil* is not effective in persons with HPV so sexually inactive girls are the ideal immunization population. Unfortunately for them, 1184 young girls were used in the clinical trials. However, with 1184, or only 5% of the 25,000 people in the trials, being sexually inactive girls, it is clear that that *Gardasil* is really an untested product for 11 and 12 year old girls. What about adverse reactions to those who have already gotten this vaccine? Now only a year and three months after the FDA's approval, the FDA's Vaccine Adverse Events Reporting System has already received 2,207 reports of adverse side effects following HPV vaccination. 2125 of those reports came in since February of 2007. This shows that the adverse effects do not always show up immediately after the vaccination, certainly not after only six months! These reports include: 31 were considered life threatening; 1,385 required emergency room visits; 451 females at the time of the report had not recovered; 51 females were disabled when the report was filed; 5 girls died, ages 12, 15, 19 and two of unknown age. According to the Judicial Watch website, one female patient died of a blood clot three hours after getting the *Gardasil* vaccine. One 12 year old girl and one 19 year old girl died from heart problems and/or blood clotting after being vaccinated. To their credit, Merck and Co has published the side effects. They warn about potential pain, fever, nausea, dizziness, and itching, some of which are typical side effects to any vaccination. Other more serious side effects that Merck has published are: paralysis, Bells Palsy, Guillain-Barre Syndrome, and seizures. These are short term reports! What will the reports be 5, 10, 15 years from now? The drug *Gardasil* is being promoted as being effective against cervical cancer, yet that disease does not develop until later in life - usually by age 50. There is absolutely no proof that girls immunized at ages 11 & 12 will even "hold" their immunity that long! A *Gardasil* vaccination now may be worthless 20 years from now or

it may have caused more serious, damaging side effects. Traditionally, the only vaccines that are mandated are drugs that have been in use for years!

3. Taxpayers could end up paying for hundreds of future medical lawsuits and wrongful death lawsuits due to this drug, if the information is coming from our own state government and local schools. Why wouldn't Merck and Co. be the recipient of these lawsuits? Because they have immunity from them! When the U.S. Centers for Disease Control recommended after insufficient studies and long time use, that girls aged 11 & 12 receive Gardasil, Merck received immunity from lawsuits under a federal program called VACCINE INJURY COMPENSATION PROGRAM, which is a public-paid insurance program. This means that Merck is legally blameless if children are injured by mandatory Gardasil vaccines and it means that the Vaccine Injury Compensation Program has to compensate them. Taxpayer money should not be used to compensate people for a drug known to have adverse reactions and that does not treat what it claims to treat.

4. I oppose this bill because of the cost to the taxpayers of Wisconsin. The cost of administering the drug Gardasil would be about \$330 to \$360 each, the highest priced vaccine ever produced. Merck would pocket 65% of that for about \$234 per person. It is hard to calculate the cost of the distributing the information as required in this bill. First the Department of Health and Family Services, which is taxpayer funded, would be spending their time and effort on collecting and passing on the information. Why is that necessary? The facts about cervical cancer and Gardasil are already known by people in the medical field. Then the information would go to schools – and from them to the parents - another mandated rule for our schools to follow but no additional funds to carry it out – another cost for each school district. Yes, they could carry this obligation out by posting it on their web sites. Easy to do, but then it is also easily available for any student going to the web site to get their assignment or grades! This bill would cause unnecessary costs to Wisconsin taxpayers.

5. How effective is the drug Gardasil against HPV? This drug is effective against only four of the 100 known strains of these viruses. These four strains are responsible for only 60% to 70% of all cervical cancers. There is another, 100% effective prevention for cervical cancer and that is abstinence – abstinence from sexual activity outside of marriage with one uninfected partner. HPV is a result of unrestricted sexual activity. To suggest that 11 and 12 year old girls be vaccinated for a disease that is caused by sexual activity, is to assume that they are going to be sexually active. Such an assumption may be true for some girls, but most certainly not all girls. Children live up to what you expect of them most of the time. If you teach and expect abstinence, most will be abstinent. If you expect promiscuity, they probably will be promiscuous. We should be teaching abstinence, and there are funds available for that. However, Gov. Doyle has directed the Department of Health and Family Services to turn down \$600,000 in Title V Federal funds because of restrictions on what they could teach when using these funds.

6. I oppose this bill because the real goal of AB 492 is to prepare the way for mandating the vaccine for all girls going into sixth grade in this state. That was the bill brought in February, 2007, which failed due to a strong public backlash to such extreme measures. Senator Taylor and Representative Grigsby have said that they would like to see the HPV vaccination mandatory and are not done with this agenda yet. This bill is a stepping stone to mandating an unsafe drug to young girls whom it won't help and will probably harm.

7. I oppose this bill because it is neither the state government's responsibility, nor right, nor duty to decide what is best for the children, including the young girls that live in this state. Our young girls do not belong to the Federal government; they do not belong to the state government; they do not belong to the school districts. They are wonderful human beings, placed in families that are responsible to bring them up to adulthood. The families that I know love their children unconditionally; they want what is best for them; they do not want to see them harmed in any way; they want to see them grow up to being responsible, mature adults. Maybe the families you know are not like that. Maybe the families are broken and your neighborhood is in ruins. Maybe in your part of the state

people are living in unsafe, unfriendly environments. If so, then make their world safer, not more dangerous by advocating, and eventually mandating the HPV vaccine Gardasil. Make their world safer by teaching and expecting abstinence. In the school district where I reside, the schools have taken driver's education out of their curriculum, and the parents are solely responsible. That is what we need to do in regards to so-called education about sexually transmitted diseases. Keep the parents responsible for their job. The government needs to stop mandating everything that is done in our schools. Stay out of families' daily lives. Please, leave our precious children alone.

In summary, I oppose AB 492/SB252 for these reasons: taxpayers should not have to pay for advertising for one specific company, or for telling people about an unsafe drug, or for funding lawsuits which the government is sure to incur. The drug being pushed is not safe, the clinical trials were totally flawed and too short, and it is only effective against some of the viruses that cause cervical cancer. AB492 would be a stepping stone to force all girls going into sixth grade to get this vaccine. That would be too much government interference in our schools and in our families.

I have a copy of my remarks, and some supporting information, for the members of the committee bringing this bill. Thank you for the opportunity to speak and thank you for listening.

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# nature biotechnology

## Flogging Gardasil

**In its rush to market its human papillomavirus vaccine, Merck forgot to make a strong and compelling case for compulsory immunization.**

Merck's human papillomavirus (HPV) vaccine Gardasil should have been an easy sell. It protects against cervical cancer, the second most common cancer among women. It demonstrates 100% efficacy in preventing infection by the two HPV types most commonly associated with that cancer. And it was endorsed by the World Health Organization and the US Centers for Disease Control's (CDC) Advisory Committee on Immunization Practices. But the company's heavy-handed lobbying of legislators seems now to have soured the reception for this important vaccine and perhaps has sullied the reputation of vaccination in general.

Each year, cervical cancer is diagnosed in ~470,000 women worldwide. Of these, one in two will die, most of them in Latin America, Africa, India and South Asia, where the resources and infrastructure to fully implement Papanicolaou (Pap) smear tests are limited. (In the past four decades, industrialized countries have cut cervical cancer mortality and incidence rates by 74% largely through the use of the Pap smear).

Virtually all (99%) cervical cancers are linked to infection with HPV, and HPV is virtually unavoidable. According to the CDC, almost 80% of US women have acquired one or more genotypes of HPV by the age of 50. Most genital infections are asymptomatic and resolve spontaneously, but the virus can persist and cause precancerous lesions that can become malignant over the subsequent 20–30 years.

Thus, a vaccine like Gardasil has a huge potential market. Based on L1-encoded virus-like particles, it protects against the HPV genotypes 16 and 18 (which account for 70% of cervical cancers) and HPV 6 and 11 (which cause >90% of genital warts and cause abnormalities or dysplasia that can confound Pap test results). And ever since Gardasil gained US Food and Drug Administration (FDA) approval last June, Merck has made no secret of its ambition to make it into a blockbuster product.

In 2005, 1,500 of its sales reps were redeployed to vaccine marketing. It ramped up contributions to political campaigns and to women's health interest groups. And in recent months, it started an unprecedented lobbying blitz, securing in 23 states legislation that would mandate vaccination of pre-teen girls. Unusually, Merck also targeted adolescents directly through television ads in which free-spirited young girls jump rope, pummel punching bags or skateboard, declaiming "one less" cervical cancer case (while mothers gently admonish, "Gardasil may not fully protect everyone" and tenderly list the side effects).

This all seemed to be working very nicely—by October last year the company had already sold ~\$80 million worth of the vaccine. But in the New Year, things began to unravel.

Religious moral crusaders, of course, already opposed the vaccine. But they were joined by an increasingly vocal group of families and consumer advocates who felt that government-mandated HPV vaccination trespassed on the right of parents to make medical decisions for their children (even though most state bills had an opt-out provision). In January, the medics joined in: the American Academy of Pediatrics and the Association

of American Physicians and Surgeons, among others, voiced concerns over patchy reimbursement, absence of safety data in the target population and the wisdom of immunizing girls against a disease that is now less prevalent in the US and that, in any case, doesn't develop until later in life (prompting the question, "Will immunity last?").

Things came to a head, though, early last month when Texas governor Rick Perry circumvented his state legislature and signed an executive order making HPV vaccination compulsory for 11- to 12-year-old girls. Adding fuel to the resulting outcry, it was revealed that Merck had contributed \$6,000 to Perry in the past and now employed Mike Toomey, a former Perry chief of staff, as its lobbyist.

Surrounded by a chorus of disapproval, Merck cracked. As *Nature Biotechnology* went to press, the company announced a cessation of all efforts to lobby for US state laws requiring compulsory vaccination.

There are several lessons from all this. First of all, make the clinical case fully. Preteens are the preferred demographic for vaccination (Gardasil is ineffective in HPV-infected subjects, so sexually inactive girls are the ideal immunization population), but only 1,184 (5%) of the 25,000 people participating in Gardasil's clinical trials were from this group. Critics could, therefore, claim that an "untested" product was being foisted onto America's children, and Merck didn't have a strong enough data-based case to allay parents' fears concerning vaccine safety. Merck's quest for compulsory immunization so soon after approval also broke with precedent for vaccines, which are usually in use for years before being mandated.

Second, if you're going to introduce the most expensive vaccine in history (\$360 for three doses) as a government-mandated prophylactic, you'd better make a solid economic case. A back-of-the-envelope calculation shows that an immunization program in 11- to 12-year-olds would cost \$30 billion (4 million children per year  $\times$  \$360  $\times$  20) in the first 20 years before Gardasil would save a single life. This is a huge initial outlay, even when the net present value of the long-term savings in reduced screening and treatment in an HPV-immune population are considered.

Finally, present the product in its full context. Gardasil is an important part of the cervical cancer management picture, but not the whole solution. Greater awareness of disease risks, safe sex, condom use and improved 'opt-in' cervical cancer screening should also have been promoted. If Merck had run a public health education campaign rather than simply plugging its product, Gardasil might have had a better reception.

It's telling that Peter Loescher, Merck's president of global human health, emphasized to Wall Street in January the need for "speed, speed, speed" in a product launch. But amid its overblown marketing blitz, the company lost sight of another important goal: full engagement with stakeholders, whether they be the media, opinion leaders, physicians, pharmacists, health workers or the general population (which ultimately pays for it all). Only after this has been accomplished should the marketers be unleashed.





# Gardasil

## Hype over health

By Bob Marshall

*Virginia Delegate Bob Marshall is an expert researcher and legislator whose fundamental concern is the rights of persons. He fought against Virginia's Gardasil mandate and his findings should alarm the citizens of all U.S. states and territories.*

Gardasil is a vaccine against human papillomavirus (HPV) types 6, 11, 16 and 18, which can lead to (or can be associated with) cervical cancer. Gardasil's maker recommends it for girls and young women ages 9-26. It received fast-track approval from the U.S. Food and Drug Administration in June 2006. Less than one year later, in May 2007, Judicial Watch released FDA documents showing that 1,637 reports of adverse reactions, including three deaths, are related to Gardasil. "One physician's assistant reported that a female patient died of a blood clot three hours after getting the Gardasil vaccine. Two other reports, on girls 12 and 19, reported deaths relating to heart problems and/or blood clotting," Judicial Watch revealed.

Gardasil is made by pharmaceutical giant Merck and it can cost from \$140 to \$275 per shot for each of the three required shots, plus an office visit charge of \$35 to \$185. This makes Gardasil the most expensive vaccine ever marketed in the United States.

The high price might be necessary to help cover the salary of Merck's CEO, Richard Clark. In February, the *Wall Street Journal* noted that Clark received \$8.4 million in income in 2006.

Merck also needs cash because of pending lawsuits from several thousand claims for damages and deaths attributed to its Vioxx painkilling drug, which was with-

drawn from the market after causing an estimated 88,000 to 139,000 heart attacks, 30-40 percent of them fatal, according to the FDA's Dr. David Graham. This could cost Merck billions.

### Government mandates

Laws mandating vaccinations were first passed in the United States to control outbreaks of smallpox. Subsequently, the U.S. government has required children to get vaccines against measles, whooping cough and polio.

However, the case for Gardasil is different because children can't catch HPV by sitting next to someone in class. HPV is sexually trans-

**THE CASE FOR GARDASIL IS DIFFERENT  
IT SOUNDS CHILDREN CAN'T CATCH HPV BY  
SITTING NEXT TO SOMEONE IN CLASS. HPV  
IS SEXUALLY TRANSMITTED.**

mitted. Therefore, the chances of grade-school girls getting HPV are next to nil.

Even prior to reports of the three deaths linked to Gardasil, Merck's mandates were not supported by the Association of Immunization Managers, which is comprised of state public health immunization officials from all state, territorial and local immunization grantees. Claire Hannan, executive director, said AIM's policy supports infrequent use of mandates and then only after a long implementation period.

Last December, the *New England Journal of Medicine* also urged caution for Gardasil mandates, stating: "The move to require

HPV vaccination raises broad questions about the acceptability of mandatory public health measures, the scope of parental autonomy and the role of political advocacy in determining how preventive health measures are implemented."

### Misleading campaigns

Merck's marketing also caused problems for Gardasil researchers such as Dr. Diane Harper, a physician and medical scientist at Dartmouth Medical School who has researched an HPV vaccine for 20 years. Her research at Dartmouth is supported by Merck, but Harper rejects the company's advertising campaign. "Merck has

not said anything incorrect, but the way they are marketing it makes it so people only hear, 'This is a vaccine that protects me from all cervical cancer.' And that's wrong," Harper told *FW Daily News* (March 14).

Dr. Harper also rejected making the vaccine mandatory. "Giving it to 11 year olds is a great big public health experiment," she warned. "There also is not enough evidence gathered on side effects to know that safety is not an issue... At 11, these girls don't get cervical cancer—they won't know for 25 years if they will get cervical cancer." Harper questioned how long the vaccine lasts and when women might need a booster. She

*from Newnan  
July 2008*



said, "To mandate now is simply to Merck's benefit and only to Merck's benefit."

Dr. Harper noted that if a woman has already been exposed to, say, HPV type 6, the Gardasil vaccine can't prevent cervical cancer from that type of HPV, but it can work against the other three HPV types.

### Merck had warning

Dr. Moira Dolan of the Texas-based Medical Accountability Network wonders if Gardasil might make things worse. She said that Merck's "study showed an increase in pre-cancer related to the vaccine types in the people who already had these infections before they got the vaccine."

The American Cancer Society reported that Gardasil clinical trials excluded women who were pregnant. However, some women did become pregnant after taking the initial dose of Gardasil. Five of 56 women who received Gardasil and became pregnant within 30 days had children with birth defects, while none of the 59 women who got pregnant within 30 days of a placebo had children with birth defects.

Like Dr. Harper, the ACS also noted that safety data for administration of Gardasil is lacking and that there is little information on the duration of immunity.

Research is very clear that smoking, a compromised immune system and birth control pills can enhance a woman's chances of getting cervical cancer. Yet abstinence, as the government calls it, is an even more certain and less costly means of preventing HPV infection. So the notion that women should resort to the most expensive vaccine in an effort to avoid cervical cancer borders on despair. Mark Iwain's quip that "virtue has

never been as respectable as money" might have been written with Gardasil in mind.

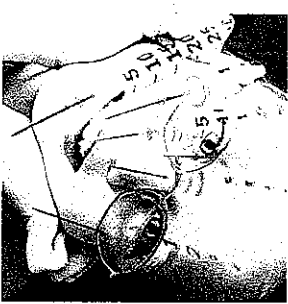
### The politics of Gardasil

"Why wouldn't you want a cure for cancer?" Such loaded questions were directed to lawmakers across America in the early months of 2007 if they hesitated to pass laws requiring 11-year-old girls to be vaccinated with Gardasil or be barred from school.

Merck's efforts to use the powers of government quickly received a boost when the U.S. Centers for Disease Control recommended that girls aged 11 and 12 receive Gardasil.

The CDC recommendation helped Merck achieve immunity from lawsuits under the federal Vaccine Injury Compensation Program (a public-paid insurance program). This means Merck is legally blameless if children are injured by mandatory Gardasil vaccines and it means the VACP has to compensate them.

In addition, children of low-income families are eligible for tax-subsidized Gardasil shots under the federal Vaccines for Children Act.



Merck ignored suggestions from the CDC's Dr. Jon Abramson and other pro-Gardasil panel mem-

bers that the company should not lobby state lawmakers to require the vaccine for school attendance.

### What money can buy

Merck was well positioned to take advantage of government connections. In 2006, Merck's political action committee made donations of \$611,975 to state lawmakers or party political action committees in 27 states.

Merck was helped by Women in Government, an organization of female state legislators and business leaders, which endorsed the mandatory vaccination program, despite the fact that Dr. Diane Harper had alerted the group of her concerns about Gardasil. As it turns out, Merck and other big pharmaceutical companies provide "support" for Women in Government, according to its web site.

Since last October, lawmakers in at least 39 states and Washington, D.C. have introduced bills mandating, funding or promoting Gardasil. In 2007, mandatory vaccination proposals were introduced in at least 24 states and the District of Columbia.

In late 2006, New Hampshire made Gardasil available free to girls under 18. And in January 2007, South Dakota Governor Mike Rounds spent \$9.2 million to vaccinate approximately 44,000 girls from ages 11 to 18.

The Gardasil hype was aided by an article in the *Journal of the American Medical Association*, which found that almost 27 percent of U.S. females aged 14 to 59—nearly 26 million women—had HPV. But the article's fine print showed that the four strains of HPV that Gardasil worked against were present in only 3.4 percent or 3.1 million females and that 90 percent of all HPV infections do not become chronic.

On February 2, 2007, Merck temporarily hit the jackpot with Texas Governor Rick Perry's executive order mandating Gardasil for all girls entering the sixth grade, with few exceptions.

Perry was criticized for his Merck connections. On February 3, KBTX-TV in Bryan/College Station, Texas reported that



"Perry has several ties to Merck and Women in Government. One of the drug company's three lobbyists in Texas is Mike Toomey, his former chief of staff. His current chief of staff's mother-in-law, Texas Republican state Rep. Dianne White Delisi, is a state director for Women in Government."

Then on February 20, Merck announced it would stop active state lobby efforts.

On February 22, ABC News cited Associated Press, stating that Perry's "Chief of staff, Deirdre Delisi's calendar shows she met with the governor's budget director and three members of his office for an HPV Vaccine for Children Briefing" on Oct. 16. That same day, the documents show, Merck's PAC donated \$5,000 to Perry and \$5,000 total to eight state lawmakers.

Later, the Texas legislature passed two bills overriding the governor's executive order.

Still, Merck's efforts did produce a Gardasil-related law in Colorado, whose legislature passed a bill allocating four percent of the tobacco lawsuit settlement money to pay for a cervical cancer immunization fund.

So far, only the Virginia legislature passed a Gardasil mandate. House Bill 2035 first passed the House of Delegates Health Committee with no parental opt-out provision, but one was added on the House floor.

I was one of only 17 delegates voting "No," while 80 voted "Yes." The Gardasil mandate returned as a Senate bill and opposition increased to 32 delegates, including myself, but it passed because 66 voted in favor of it.

Governor Tim Kaine sent an amendment back to the legislature that gave parents broad discretion to refuse Gardasil after receiving information about the vaccine. The legislature approved his amendment and, in April, Kaine signed the bill into law against the December 2006 backdrop of Merck announcing the \$57 million expansion of its Elkhon, Virginia plant. Gov. Kaine's approval of a \$700,000 grant from the Virginia Investment Partnership for Merck to improve its Elkhon plant is also in place. Currently, the annual payroll at this plant is \$60 million and the expansion is set specifically for producing Gardasil.

So, Gardasil is big business and the dangers of mandating it cannot be overemphasized.

Bob Marshall is a member of the Virginia House of Delegates, representing the 15th district of the Commonwealth.

<sup>1</sup> American Cancer Society Guidelines for Human Papillomavirus (HPV) Vaccine Use to Prevent Cervical Cancer and Its Precursors, 2007.

E-mail this article from our web site [www.ColebretnLife.org](http://www.ColebretnLife.org).



# The Banner



September/October 2007

"Defending God's Plan"

Pro-Life Wisconsin

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Don't forget to register for  
PLW's Fall Auction Dinner!

Pro-Life Wisconsin  
19270 North Hills Drive  
Brookfield, WI 53045

Tel: 262-796-1111  
1-877-GOD'S WILL  
Fax: 262-796-1115

info@prolifewisconsin.org  
www.prolifewisconsin.org

## Pro-Life Wisconsin to mark fifteen years at upcoming Annual Auction Dinner, September 28

Brookfield -- Pro-Life Wisconsinites will gather from across the state at the Country Springs Hotel September 28 in Pewaukee to celebrate fifteen years of pro-life advocacy.

PLW has come together as a family many times in the past fifteen years, but you won't want to miss this year's Auction Dinner. The evening features beloved Milwaukee sportscaster, Tom Pipines, as celebrity emcee, as well as keynote speaker David Bereit, national director of the 40 Days for Life campaign. You will be inspired as we re-cap PLW's fifteen years of no-compromise pro-life activism. Seats are still available - but you'll have to act fast! Seats are \$50 per person, \$475 per table of ten. Advanced reservations are required.

Call 877-GODS-WILL (463-7945) to reserve your seat today!



Our Guest Speaker  
**David Bereit**  
national campaign  
director  
40 Days for Life

Our Celebrity Emcee  
**Tom Pipines**  
Milwaukee sportscaster

## HPV vaccine mandate dropped in favor of educational approach

*Adverse effects of Gardasil alarming*

**Brookfield** - Standing up for the rights of parents to protect their children, Pro-Life Wisconsin earlier this year voiced our strong opposition to the "Cervical Cancer Prevention Bill." The proposed legislation would require all girls entering the sixth grade in Wisconsin's public, private and charter schools to be vaccinated with the human papillomavirus (HPV) vaccine. The Food and Drug Administration (FDA) approved the HPV vaccine *Gardasil* in June 2006 for females

aged 9 to 26 after a six-month review, citing its effectiveness against four HPV strains that cause 70 percent of all cervical cancer. Since then bills similar to the Wisconsin proposal have sprung up in at least a dozen other states, many meeting with opposition from parents, physicians, and consumer advocates concerned about the government's encroachment on the parent-child relationship and the vaccine's safety and effectiveness.

(cont. p. 6)

## Seizures and other side effects just a few of the many problems with Merck's HPV Vaccine

(cont. from p. 1)

Fortunately, the co-authors of the proposal, Senators Lena Taylor (D-Milwaukee) and Robert Wirth (D-Kenosha), have dropped the requirement that young girls get vaccinated against HPV and have instead opted for an educational approach that informs schools and parents about the human papillomavirus and the risks and benefits of vaccination. It is one thing for the state to merely inform parents of the vaccine's availability, as it does for the meningococcal (meningitis) vaccine. It is quite another thing for the state to make it mandatory for entrance into our schools. It was the state's presumptuousness and intrusiveness that prompted our opposition to the original legislation.

Senators Taylor and Wirth, along with Representatives J.A. "Doc" Hines (R-Oxford) and Tamara Grigsby (D-Milwaukee), have introduced legislation (SB 252 and AB 492) that would direct the Department of Health and Family Services (DHFS) to collect information about the human papillomavirus, including the causes and symptoms of the virus, how it is spread, how it may be prevented, how to obtain additional information about the virus, and the availability, effectiveness and risks of vaccination against the virus. DHFS must make the collected information available to school districts, private schools, and charter schools. Likewise, each school board and the governing body of each private school and charter school must provide the parents and guardians of pupils enrolled in grades 6 to 12 with the collected information. DHFS and schools may satisfy this informational directive by simply posting the information on their respective Internet sites.

Despite the HPV vaccine's moral neutrality (it was not derived from aborted fetal tissue, for example), there is a growing concern about its safety and effectiveness. The FDA's Vaccine Adverse Events

Reporting System has already received 2,207 reports of adverse side effects following HPV vaccination with Gardasil, up from 82 reports in February. Of the reports:

- 31 were considered life threatening;
- 1,385 required emergency room visits;
- 451 females at the time of the report had not recovered;
- 51 females were disabled when the report was filed;
- 5 girls died, ages 12, 15, 19 and two of unknown age.

According to the Judicial Watch website,

*"Three deaths were related to the vaccine. One physician's assistant reported that a female patient 'died of a blood clot three hours after getting the Gardasil vaccine.' Two other reports, on girls 12 and 19, reported deaths relating to heart problems and/or blood clotting."*

*"Side effects published by Merck & Co. warn the public about potential pain, fever, nausea, dizziness and itching after receiving the vaccine. Indeed, 77% of the adverse reactions reported are typical side effects to vaccinations. But other more serious side effects reported include paralysis, Bells Palsy, Guillain-Barre Syndrome, and seizures...It looks as if an unproven vaccine with dangerous side effects is being pushed as a miracle drug."*

As for Gardasil's effectiveness, physicians and public health officials disagree over whether it is a cure-all for cervical cancer. Clayton Young, an obstetrician-gynecologist in Texas, challenges the claim that Gardasil will prevent cervical cancer. "There is no proof Gardasil will stop cervical cancer," he said. "They haven't been studying it long enough to make that claim." Pro-Life Wisconsin will continue to monitor this legislation.

### Gifts from IRA's Tax Free through 2007

Thanks to the Pension Protection Act of 2006, if you are over 70½, you can donate up to \$100,000 as a direct gift to Pro-Life Wisconsin Education Task Force from your traditional IRA or Roth IRA without paying federal income tax! Money in an employer's 401(k) or similar plan can be transferred into an IRA in order to make a charitable contribution. Act quickly as this legislation is only valid through the 2007 tax year. Consult your tax specialist for details.



## ROBERT W. WIRCH

STATE SENATOR TWENTY-SECOND DISTRICT

September 26, 2007

TO: Members of the Assembly Committee on Public Health  
Representative J.A. Hines, Chair  
FROM: Senator Bob Wirch  
RE: Testimony in favor of AB 492

---

According to the Center for Disease Control at least 50% of sexually active people will get a form of the human papillomavirus (HPV) and most won't know that they have it. I believe AB 492 will provide parents and women the information they need about HPV and its links to cervical cancer so that they have the tools to make good health choices.

HPV is not a new virus, but many people are not aware of it because it usually has no symptoms and most cases of HPV go away on its own – without causing any health problems. However, certain strains of HPV do cause major problems that women and families need to be aware of. High – Risk HPV is linked to cervical cancers if not treated.

Cervical cancer is the second most common cancer among women worldwide and over 70% of cases were linked to HPV. There are an estimated 10,300 cases of cervical cancer causing 3,700 deaths each year in the U.S. and 50% of women diagnosed with cervical cancer are between 35 & 55 years old, a time of peak family responsibility and economic productivity. I believe that it is important to know about and understand the link between HPV and cervical cancer. Providing women and their daughters with information about HPV and prevention, lives will be saved.

The CDC recommends two ways to prevent cervical cancer. The first is that women should get regular pap tests to look for cell changes caused by HPV. Pap tests find cell changes early so that the cells can be treated before they turn into cancer.

The second way is to get an HPV vaccine. The vaccine protects against four types of HPV and is given through a series of three shots over a six – month period. It is recommended for 11 – 12 year old girls along with a “catch up” for young women aged 13 – 26 who have not yet received or completed the vaccine series.

I believe that making sure young women and their families are aware of HPV and its links to cervical cancer will reduce the cases of cancer that we see significantly. It is imperative that we talk about this virus and the ways that young women can go about protecting themselves against it.

I urge you to pass Assembly Bill 492 as written.





Eagle Forum of Wisconsin  
P.O. Box 86  
Brookfield, WI 53009

To Honorable Members of the Committee on Public Health

Chairman Representative J.A. Hines, Vice Chair Rep. L. Vukmir, Rep. J. Ballweg,  
Rep. T. Moulto, Rep. I. Nerison, Rep. C. Benedict, Rep. S. Wasserman,  
Rep. M. Schneider, Rep. S. Black

Re: Assembly Bill 492 HPV Informational Mandate

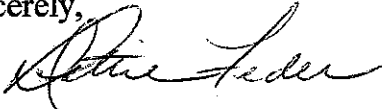
With reference to mandatory dissemination of information concerning HPV and a newly developed vaccine, a great deal of controversy and disagreement make this bill premature. Until accurate scientific information is written, it would be a mistake to advance this bill.

Several months ago, Eagle Forum of Wisconsin forwarded to all legislative offices information released by independent researcher, scientist, physician and professor, Diane M. Harper, of Dartmouth Medical School in New Hampshire who stated the vaccine is inappropriate for young girls, and instead should be administered to women over the age of 18 after doing vaginal swabs. Vaginal swabs are not appropriate for little girls. Dr. Harper is the nation's foremost researcher on the issue, and her work does not contain the influence of pharmaceutical corporate funding. Dr. Harper cautions against vaccinating before girls are sexually active, which could backfire by giving a false sense of protection. She stated vaccinating too soon could actually cause the rate of cancer to rise. The vaccine is not a cancer cure and will still necessitate the need for pap smears.

In addition to the premature nature of this bill, there is an increasing concern of the safety of this vaccine. Contrary to initial reports, many serious side effects, including death, have been reported after the administration of the vaccine. Further studies are needed to determine the effectiveness, term of immunity and adverse reactions. The State of Wisconsin might be exposed to liability by promoting a vaccine with questionable safety.

We urge you to reject mandating the release of information that is yet unproven and unwritten by the Department of Public Instruction in conjunction with the Department of Health and Family Services.

Sincerely,



Dottie Feder, President  
Eagle Forum of Wisconsin

Dear Mr. [Name]  
[Address]  
[City, State, Zip]

Enclosed please find [Number] copies of [Document Name]

I am sure that you will find this information of interest. I have been working on this project for some time and I believe that the results are quite significant. I have also included a copy of the [Document Name] for your reference.

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Sincerely,  
[Signature]  
[Name]  
[Title]  
[Organization]

To Chairman J.A.Hines:

September 26,2007

Dear Chairman Hines and members of the Public Health Committee,

Thank you for holding this hearing on a very important bill.

I oppose AB 492. When the mandate bill was strongly opposed, Sen, Taylor decided to go for an "education" bill. The ultimate goal, however will be a mandate. I remember her saying that this bill, AB 492 will be a first step. Nothing short of a mandate will please her or Merck Drug Company.

As a retired pharmacist, I think the vaccine is unproven and could be dangerous..It disturbs me that Merck Company achieved **immunity from lawsuits** under the Federal Vaccine Injury Program (VICP) , a public paid insurance program. Merck is **blameless** if children are injured or killed by the vaccine, leaving the VICP to foot the bill ( meaning we, the taxpayers get to pay!!)

I have another interest in this program. I have five granddaughters many in this age range, one in Milwaukee and four in Georgia . **I don't want them used as human guinea pigs!**

Other reasons I object to the bill:

Legislators will be voting on information they will not review, turning it over to an agency that is probably pro-HPV Vaccine and will skew the information to get the results they are seeking.

Not appropriate for girls under 18 years of age. This is what independent researcher, Dr. Diane Harper, of Dartmouth Medical School has said. She has researched the virus and vaccine for 20 years.

Vaccinating before a girl is sexually active sends the **WRONG MESSAGE**, It assumes promiscuity.

Lack of information on duration of protection and serious side effects. (Including deaths)

Schools will be used as an advertising tool of the drug companies.

Thank you for reading this and I hope you will consider my remarks.

Joan Tatarsky  
5229 No. 107<sup>th</sup> St.  
Milwaukee ,WI 53225  
Harper





## PLANNED PARENTHOOD ADVOCATES OF WISCONSIN

To: Chairman Hines & Committee Members Vukmir, Ballweg, Moulton, Nerison, Benedict,  
Wasserman, Schneider and Black  
From: Chris Taylor; Nicole Safar  
Planned Parenthood Advocates of Wisconsin  
Re: Please Pass the Cervical Cancer Vaccine Education and Recommendation bill, SB 252 &  
AB 492  
Date: September 25, 2007

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Planned Parenthood Advocates of Wisconsin commends the committee for addressing the crucial issue of cervical cancer and its prevention in Wisconsin. The awareness campaign required by this bill is a critical first step in educating the public, and specifically parents of girls, about the causes of cervical cancer and how to best prevent it. Please pass AB 492/SB 252 and encourage leadership to hold a timely vote on it.

Cervical cancer was once the leading cause of cancer death among women in the United States and it remains the 2<sup>nd</sup> leading cause of cancer deaths among women world wide. However, due to increased screening and early detection efforts in the U.S., deaths have decreased significantly in the last 40 years. While progress has been made, about 10,000 women annually will develop cervical cancer and about 4,000 will die from it. We now know more about cervical cancer and its causes than ever before—science has made amazing breakthroughs regarding the detection and prevention recently.

According to the National Cancer Institute, human paillomaviruses (HPV) are a group of more than 100 viruses, which include over 30 viruses that are passed through sexual contact. Most people who develop an HPV infection do not show any symptoms and the infection goes away without any treatment. However, several strains of HPV are now recognized to be the major cause of cervical cancer—specifically strains 16 & 18 cause over 70% of all cervical cancers. The other common HPV strains passed through sexual contact, strains 6 & 11, are responsible for over 90% of all genital warts. According to a recent study by the Journal of the American Medical Association, HPV is the most common sexually transmitted infection in the U.S. The prevalence of HPV among the overall population in the U.S. is estimated to be about 27%. However, HPV prevalence among young women is much higher: about 25% of young women age 14-19 have HPV and nearly 45% of young women 20-24.

The good news is that 2006, the federal Food and Drug Administration (FDA) approved the HPV vaccine Gardasil. Gardasil is the first ever cancer vaccine. It has been shown to protect against at least 4 of the most dangerous strains of HPV that cause cervical and other reproductive cancers. The FDA approved the vaccine for girls and young women ages 9-26; and shortly following that approval, the Center for Disease Control's Advisory Committee on Immunization Practices voted unanimously to recommend that all girls 11 and 12 receive the vaccine.

In clinical trials, the Gardasil offered almost 100% protection against at least four HPV types: 6, 11, 16 & 18. Thus far, Gardasil has been shown to be extremely safe and effective. Prior to FDA approval, the HPV vaccine was tested in more than 20,000 young women throughout the world, including in the U.S. without any serious health consequences. The experiences of patients receiving the vaccine since FDA approval have been consistent with the clinical trials and are consistent with typical immune responses to vaccines. Side effects have included soreness at the injection site, redness, tenderness, and swelling. The vaccine has been in high demand in states like New Hampshire and South Dakota, where the state is



paying for all young women to get vaccinated. In fact, many providers nationwide have been unable to keep the vaccine in stock for patients.

The HPV vaccine Gardasil is a major scientific breakthrough and a huge step toward eradicating cervical cancer in our lifetime. The Cervical Cancer Vaccine Education and Recommendation is an important and necessary plan to increase awareness and access to information about the causes of cervical cancer and the new methods of prevention which may one day end cervical cancer in Wisconsin.

I hope the committee will pass this important bill as a necessary step to making sure that at some point in the future, no woman dies of cervical cancer.

